UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CELSIS IN VITRO, INC. a Maryland Corporation, Plaintiff, v. CELLZDIRECT, INC., a Delaware Corporation and wholly-owned subsidiary of INVITROGEN CORPORATION; and INVITROGEN CORPORATION, a Delaware Corporation. Defendants.	Case No. 1:10-cv-004053 Judge Milton I. Shadur Magistrate Judge Martin C. Ashman

CORRECTED MEMORANDUM IN OPPOSITION TO

PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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I. INTRODUCTION

Plaintiff's motion for a preliminary injunction should be denied because Celsis In Vitro, Inc. engaged in inequitable conduct before the patent examiner, because its patent is invalid, because defendants have not infringed the patent, and because the drastic and extraordinary relief sought is plainly not warranted.

In 2005, Celsis filed a patent application with the Patent and Trademark Office, claiming multi-cryopreservation of hepatocytes as a new method. However, the scientific community had already been freezing and thawing hepatocytes with a high level of viability for years. Unsurprisingly then, the Examiner repeatedly rejected Celsis's application because its method was an obvious extension of the prior art.

In order to overcome these rejections for obviousness, Celsis set out to convince the Examiner that it is extremely difficult to maintain sufficient viability of hepatocytes after even one round of cryopreservation, and that a second cryopreservation could not be expected to produce viable hepatocytes. In support of these propositions, Celsis intentionally submitted misleading written submissions to the Examiner.

First, Celsis quoted an extensive excerpt from a review article that it claimed as solid support for Celsis's position, but Celsis had deceptively deleted significant information and references that directly contradicted Celsis's position and were material to patentability. Second, Celsis submitted the results of the inventor's own experiments, but failed to disclose that the methods used were scientifically invalid, and the data submitted were flawed and intentionally misleading.

Celsis is not entitled to the extraordinary relief of pulling a competitor's product from the scientific research market. First, the '929 patent is not enforceable due to Celsis's inequitable

conduct – its intentional misrepresentations to the patent examiner. Furthermore, the '929 patent is invalid because of obviousness – the claimed methods simply combine methods well known in the prior art. Moreover, the '929 patent is invalid because it violates the statutory written description requirement, in that the patent's claims are not described in the specification. In addition, defendants have not infringed the patent. Finally Celsis cannot meet the other requirements for injunctive relief because it will not suffer irreparable harm, and both the balance of hardships and public interest factors favor defendants.

II. SUMMARY OF FACTS

A. CELSIS OBTAINS THE '929 PATENT IN OCTOBER 2009.

Celsis obtained Patent No. 7,604,929 on October 20, 2009.[1] (Declaration of Michael K. Kirschner in Opposition to Plaintiff's Motion for Preliminary Injunction ("Kirschner Declaration"), Ex. 24.)[2] The '929 patent claims an allegedly novel method for preserving hepatocytes: cryopreserving and thawing the hepatocytes multiple times. (*Id.*) To obtain this patent, Celsis claimed that the concept of multi-cryopreservation was not an obvious application of known scientific methods.

Celsis obtained its patent after repeated rejection of its application by the PTO.[3] (*See* Exs. 6; 8; 10.) The PTO concluded over and over again that Celsis's approach to freezing and thawing hepatocytes was merely an obvious extension of the prior art, which taught all the key steps of the cryopreservation process. (*Id.*) In an effort to contest these findings of obviousness, Celsis repeatedly argued that researchers had previously been unable to sufficiently

[1] Because the actions of the patent applicants and their agents during the patent prosecution process are imputed to Celsis, this opposition refers collectively to the patent applicants, their agents, and Celsis as "Celsis."

[2] All references to exhibits, without additional citation, refer to those attached to the Kirschner Declaration.

[3] The key documents from Celsis's patent prosecution history, such as PTO office actions and Celsis's replies, are attached to the Kirschner Declaration.

maintain the viability of hepatocytes after cryopreservation. (*E.g.*, Ex. 7 at 12; Ex. 9 at 10.) According to Celsis's misleading submissions, its ability to freeze and thaw hepatocytes multiple times and still maintain sufficiently high levels of hepatocyte viability was an unexpected scientific advancement. (*E.g., Ex. 7 at 14; Ex. 9 at 11*)

The Examiner ultimately allowed Celsis's 11 method claims.[4] (Ex. 23.) She did so in reliance on Celsis's calculated misrepresentations, thereby wrongly concluding that "[t]he prior art teaches that hepatocytes are extremely difficult to work with and that it is extremely difficult to maintain a sufficient level of viability of hepatocytes during even one round of cryopreservation and thawing." (*Id.* at 2.)

B. ALL TECHNIQUES DESCRIBED IN THE '929 PATENT HAD BEEN TAUGHT BY THE PRIOR ART.

Despite Celsis's characterizations to the contrary, the scientific community had for years been achieving high levels of hepatocyte viability after cryopreservation. Scientists began developing procedures for storing hepatocytes in the late 1980s. (Declaration of Albert Li ("Li Decl.") ¶ 3.) As described by the field's leading expert, Dr. Albert Li, by the mid-1990s, it was common practice for researchers to use cryopreserved hepatocytes. (*Id.* ¶ 3.) Hepatocytes from multiple individuals began to be routinely pooled by the mid- to late-1990s in order to provide greater predictability in drug research. (*Id.* ¶ 4.)

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[4] Claims 1 and 10 are the only independent claims. While claims 1-9 and 11 recite a method for ***making*** multi-cryopreserved hepatocyte preparations, claim 10 is an independent claim that recites a method of ***using*** multi-cryopreserved hepatocytes in *in vitro* drug studies. The Examiner appears to have been confused, and inadvertently allowed claim 10. In the "Examiner's Statement of Reasons for Allowance," the Examiner noted that "[t]he claimed invention is drawn to a method of producing multi-cryopreserved hepatocytes . . . ." (Ex. 23 (August 20, 2009 Notice of Allowability) at 2.) The Examiner clearly did not realize that a different method (namely, a method of *using* multi-cryopreserved hepatocytes) was among the allowed claims.

The Examiner's confusion was likely caused by Celsis's repeated omission of pending claim 20 (which became issued claim 10) from its list of independent claims. In its June 22, 2009 Amendment and Reply, Celsis stated as follows: "Claims 1-7, 9-17, and 19-22 are pending in the application, *with claims 1 and 10 being the independent claims*." (Ex. 19 at 12 (emphasis added).) Celsis repeated this misstatement in its July 27, 2009 Amendment and Reply, in which it stated: "Claims 10-17, 19, and 22 are pending in the application, *with claim 10 being the independent claim*." (Ex. 22 at 5 (emphasis added).)

The cryopreservation process became a viable technique for storing hepatocytes because researchers were able to achieve high levels of viability. In 1996 and 1998, respectively, de Sousa *et al.* and Ulrich *et al.* taught that the cryopreservation process, in the absence of a step to separate viable from non-viable cells, resulted in a 5-15% decrease in hepatocyte viability. (Report of Sanjeev Gupta, M.D., ("Gupta Report", attached as Exhibit A to the Declaration of Sanjeev Gupta), Ex. 14 (de Sousa et al.) at 353-54, and ex. 9 (Ulrich et al.) at 31-32; *see also* Li Decl. ¶ 5 (describing his and other researchers' viability rates of at least 70% after thawing).) De Sousa *et al.* further teaches that separating viable and non-viable cells after thawing cryopreserved hepatocytes yields more than 92% viable hepatocytes. (Gupta Report, Ex. 14 at 354.) By the late 1990s, the scientific community had achieved considerable success cryopreserving with high levels of viability. (Li Decl. ¶¶ 3, 5.)

C. EXAMINATION OF CELSIS'S PROSECUTION HISTORY REVEALS INEQUITABLE CONDUCT.

In its zeal to persuade the Examiner to reverse her findings of obviousness, Celsis filed written submittals to demonstrate the difficulty of maintaining a sufficient level of hepatocyte viability after cryopreservation. (Ex. 7 at 11-16; Ex. 9 at 8-12.) Celsis's submissions were intentionally deceptive: they blatantly mischaracterized prior art, selectively omitted highly relevant portions of a scientific article, and intentionally included experimental results based on the use of substandard cryopreserved hepatocytes.

Celsis provided the Examiner with a lengthy quotation from a review article by Terry *et al*., purportedly favorable to Celsis's position. (Ex. 7 (December 14, 2007 Amendment and Reply) at 12.) Celsis characterized *Terry et al.* as teaching that hepatocyte viability was difficult to obtain after freezing and thawing. (*See id* at 13.) However, Celsis systematically deleted the

most relevant portions of *Terry et al.* relating to the viability of hepatocytes after cryopreservation – statements that plainly contradicted Celsis's claims of novelty.

In its deletions, Celsis cut from its quotation the following summaries of prior art, which would have undermined its arguments to the Examiner:

> With human hepatocytes this decrease [in the trypan blue membrane integrity assay] can be a 20-30% drop after cryopreservation [20, 29, 33, 67]. **Some authors, however, have found that human hepatocyte viability can be maintained after cryopreservation [17, 26, 96].**
>
> * * *
>
> A common observation is that, **although hepatocyte viability may remain comparable to that of fresh hepatocytes after cryopreservation,** a much smaller percentage will be able to attach to the culture substrate (usually collagen) [28, 100].

(Ex. 7 (Ex. A at 154).) (emphasis added)

Furthermore, Celsis did not disclose several publications cited in Terry *et al.*, including de Sousa *et al.* (reference 26 in Terry *et al.*) and Ulrich *et al.* (reference 96 in Terry *et al.*). Both of these publications contradicted Celsis's misleading assertion that researchers had been unable to obtain high levels of hepatocyte viability after cryopreservation and were, therefore, material to patentability.

Despite the references cited in *Terry* et al., Celsis baselessly argued to the PTO:

- "The state of the art, as disclosed in the cited references, would not have imparted to one of ordinary skill in the art <u>any</u> expectation of success for the multi-cryopreservation of hepatocytes." (Ex. 9 at 10 (emphasis in original).)
- Based on the prior art, a second round of cryopreservation would bring "the viability to approximately *50%, at most*." (Ex. 19 at 15 (emphasis added).)

These statements were materially misleading.

In further support of its argument that its method was not obvious, Celsis submitted misleading declarations from Daniel Dryden, an inventor, to overcome the Examiner's

obviousness rejections. (Exs. 13; 20.) These declarations were provided to persuade the PTO that Celsis's cryopreservation methods had unexpected superior properties and advantages. In its June 22, 2009 Amendment and Reply, Celsis argued that, unlike the prior art, "the multi-cryopreserved hepatocyte preparation of the present invention has a significantly higher viability and metabolic activity when compared with a singly-cryopreserved hepatocyte preparation, and an unpooled but multi-cryopreserved preparation." (Ex. 19 at 14.) In support of its arguments, Celsis relied upon the June 22, 2009 Dryden Declaration. (*Id*.)

In that declaration, Dryden suggested that the multi-cryopreserved hepatocytes produced by his method unexpectedly possessed higher viability as compared with the single-cryopreserved hepatocytes. Dryden claimed that single-cryopreserved hepatocytes had 61% viability, whereas unpooled and pooled multi-cryopreserved hepatocytes prepared using the patent process had 77% and 85% viabilities, respectively. (Ex. 20 ¶ 6.) This data was used to convince the Examiner that the "inventive" step of re-freezing the hepatocytes actually **increased** viability. However, the Dryden Declaration did not disclose two critical facts that make these results meaningless.

First, the low viability of single-cryopreserved hepatocyte preparations was a result of Dryden's deliberate use of inferior hepatocytes as a starting material in the study. In his deposition, Dryden admitted that he used comparative poor quality cells with an average viability of 61% and reserved high viability hepatocytes for sale to Celsis's customers. (Ex. 25, (Dryden Dep.) at 193.) Second, unlike the single-preserved hepatocytes, the multi-preserved hepatocytes underwent density gradient centrifugation to separate viable from non-viable hepatocytes before viability was quantified. (*Id.* at 194-95.) Dryden relied on these two critical differences to intentionally skew the results to strongly favor the outcome Celsis desired.

Consequently, Celsis's conclusion that "the present invention has a significantly higher viability and metabolic activity when compared with a singly-cryopreserved hepatocyte preparation" was scientifically flawed and baseless, and the Examiner had no way of knowing this.

Furthermore, during the patent prosecution process, Celsis apparently made little or no effort to gather and disclose prior art to the Examiner. Dryden was obligated to disclose to the PTO information material to patentability (37 C.F.R. § 1.56). He confirmed his understanding of his obligation in his Declaration for Patent Application. (Ex. 2.) Nevertheless, Dryden admitted that he does not recall ever gathering prior art for submission to the PTO. (Ex. 25 (Dryden Dep.) at 120-21,177-78.) Indeed, he admits he did not give any prior art to his attorney or patent agent, and he does not recall their asking for these materials despite the duty of candor owed. *Id.*

D. LTC STARTS SELLING MULTI-CRYOPRESERVED HEPATOCYTES IN EARLY 2008.

Defendants, CellzDirect, Inc. and Life Technologies Corporation (collectively "LTC"), have been engaged in hepatocyte research and production for many years. Cryopreserved hepatocytes became a far more commercially viable product in 2006, when the Federal Drug Administration released a guidance document that identified cryopreserved hepatocytes as appropriate models for drug interaction studies. (Li Decl. ¶ 6.) The FDA guidance created a new demand for pooled multi-cryopreserved products from academic and industry researchers. (*Id.*) To respond to this demand, in December 2007, Advanced Pharmaceutical Sciences, Inc. ("APS"), developed a protocol to cryopreserve pooled human hepatocytes. (*Id.*) Developing this straightforward procedure took APS just a single day, and was done without reference to Celsis's patent application. (*Id.*) Beginning in February 2008, APS began to produce multi-cryopreserved hepatocytes for distribution by CellzDirect, LTC's subsidiary.

Well before the '929 patent issued, Celsis was aware that CellzDirect was selling pooled multi-cryopreserved hepatocytes. (Declaration of Judy Madden at ¶ 13; Declaration of

Markus Hunkeler ("Hunkeler Decl.") ¶ 4.) Yet Celsis did not request expedited prosecution or issuance of the '929 patent. Although the patent was issued in October 2009, Celsis did not file suit for another eight months.

III. ARGUMENT

Granting a preliminary injunction in a patent case is a "drastic and extraordinary remedy that is not to be routinely granted." *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry.*, 357 F.3d 1319, 1324 (Fed. Cir. 2004) (internal citation omitted). A plaintiff must establish *both* a likelihood of success on the merits *and* irreparable harm. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001).

A. CELSIS CANNOT DEMONSTRATE A LIKELIHOOD OF SUCCESS ON THE MERITS.

Most fundamentally, Celsis is not entitled to a preliminary injunction because it is unlikely to succeed on the merits of its claims. "[A]t the preliminary injunction stage, because of the extraordinary nature of the relief, the *patentee* carries the burden of showing likelihood of success on the merits with respect to the patent's validity, enforceability, and infringement." *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991) (emphasis in original).

Because LTC raises a "substantial question" concerning the invalidity, unenforceability, and infringement of the '919 patent, the preliminary injunction should not issue. *See Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1379 (Fed. Cir. 2009). A "substantial question" exists because Celsis cannot establish that LTC's defenses "lack[ ] substantial merit." *Id*.

1. The '929 Patent is Unenforceable Due to Celsis's Inequitable Conduct.

A preliminary injunction is not warranted here because there is a substantial question regarding inequitable conduct. *See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough*

Corp., 68 F. Supp. 2d 508, 552-53 (D. N.J. 1999) (denying preliminary injunction where applicant failed to disclose information to the PTO); *Ranbaxy Laboratories Ltd. v. Abbott Labs.*, No. 04 C 8078, 2005 WL 3050608 at *9 (N.D. Ill. Nov. 10, 2005) (denying preliminary injunction where applicant did not disclose test results); *Nutrition 21*, 930 F.2d at 870-71 (reversing district court grant of injunction in part due to failure to address inequitable conduct regarding erroneous declarations to the PTO). Celsis, "with intent to mislead or deceive the examiner, fail[ed] to disclose material information [and] submit[ted] materially false information to the PTO during prosecution." *See Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006).

As an applicant, Celsis had a duty of candor and good faith, and was required to disclose material information regarding its invention. 37 C.F.R. § 1.56. As stated by Patent Rule 56, this duty is intended to protect the public interest:

> A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability.

Celsis obtained its patent by repeatedly and deliberately disregarding the duty of candor. Celsis began submitting misleading materials to the PTO immediately upon receiving its first rejection on the basis of obviousness. (*See* Ex. 7 at 12.) Celsis repeatedly argued to the Patent Examiner that prior researchers had been unable to maintain hepatocyte viability over 70% after freezing and thawing. (*See* Ex. 7 at 12-14; Ex. 12 at 9-10; Ex. 13 ¶ 7; Ex. 17 at 14.) Celsis systematically hid from the Examiner prior art that contradicted its position and that would render the patent invalid. Celsis also submitted a declaration from its inventor that presented intentionally flawed and unreliable research results that ostensibly supported its novelty arguments. (*See* Ex. 20) In light of this inequitable conduct, the '929 patent is unenforceable.

Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1322 (Fed. Cir. 2008) (stating that a finding of inequitable conduct with respect to any one claim of the patent renders the entire patent unenforceable.)

Celsis's misrepresentations and omissions were highly material. The information is material because a reasonable Examiner would consider it important to know the true facts in deciding whether to issue the '929 patent. *Digital Control,* 437 F.3d at 1315-17. Information concealed from the PTO may be material even if it would not invalidate the patent. *See Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1187 (Fed. Cir. 2006).

Celsis's misrepresentations and omissions from Terry *et al*. were highly material and made with intent to mislead the Examiner. Furthermore, de Sousa *et al.* and Ulrich *et al.*, which were cited in Terry *et al.*, taught that viabilities of hepatocytes following cryopreservation without Percoll separation were as high as 85%, and with Percoll separation as high as 92.5%. (*See* Gupta Report ¶¶ 27, 29.) Based on Celsis's willful deletion of these references, Celsis was unquestionably aware of the prior art undermining its claims. The intentional mischaracterization and omission of this prior art also leads to the obvious conclusion that Celsis intended to mislead the PTO. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed. Cir. 1995). ("Intent need not be proved by direct evidence; it is most often proven by a showing of acts, the natural consequence of which are presumably intended by the actor."). Under the circumstances presented here, both materiality and intent are very high.

Daniel Dryden's research regarding cryopreserved hepatocyte viability was equally critical in the patent process: hepatocyte viability was the PTO's key metric throughout Celsis's patent prosecution. As such, it was essential that Dryden present a complete and accurate description of his materials and methods. Instead, he skewed his research by intentionally

selecting substandard hepatocytes for comparison with those subjected to the claimed process and by using inconsistent methodologies. There is little question that Dryden's omissions in his Declaration were intended to mislead the PTO: if the Examiner had understood his "research," Dryden's conclusions would have carried little weight.

Pharmacia Corp. v. Par Pharmaceutical, Inc., 417 F.3d 1369, 1370 (Fed. Cir. 2005), provides guidance regarding the consequences of such conduct. In *Pharmacia*, a pharmaceutical company applied for a patent for generic medication. *Id.* at 1370. The initial application was rejected on the grounds of obviousness. *Id.* at 1371. Like Dryden, the applicant in *Pharmacia* then submitted an argument that its invention was not obvious, relying upon a 37 C.F.R. § 1.132 declaration. In the declaration, a researcher compared the characteristics of two compounds. *Id*. The declaration conflicted with a prior article by the researcher and made a misleading "implicit suggestion" regarding his test results. *Id.* at 1371-72. The district court found that when the researcher submitted the declaration, he knew or should have known it was inaccurate and misleading. The court deemed the declaration "highly material" because it played an important role in overcoming the PTO's rejection for obviousness. *Id.* at 1372. Accordingly, the district court and the Federal Circuit agreed that the subsequently issued patent was unenforceable due to the applicant's inequitable conduct. *Id* at 1372-74. Dryden's conduct should lead to the same finding here.

Finally, the inventor's failure to fulfill his disclosure obligations provides an additional ground for finding inequitable conduct. As admitted by Dryden, he does not recall ever gathering prior art for the PTO. Similarly, he did not provide prior art to his attorney or patent agent, and he does not recall even being *asked* for such materials. (Ex. 25 (Dryden Dep.) at 120-21, 177-178.)

Patent applicants have a duty to treat the PTO, and by extension the public, fairly. The conduct exhibited by Celsis cannot be tolerated, and the Court should refuse to issue a preliminary injunction due to the unenforceability of the '929 patent.

2. The '929 Patent is Invalid Due to Obviousness.

Examination of relevant prior art and the '929 patent raises a substantial question about its validity. This "substantial question" showing requires less proof than the clear and convincing standard required to prove invalidity at trial. *Titan Tire*, 566 F.3d at 1379-80*; Erico Int'l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1356 (Fed. Cir. 2008). The Federal Circuit has explained that:

> In resisting a preliminary injunction . . . one need not make out a case of actual invalidity. *Vulnerability* is the issue at the preliminary injunction stage, while *validity* is the issue at trial.

Amazon.com, 239 F.3d at 1359 (emphasis added).

Every step in the method of creating and using the multi-cryopreserved hepatocytes claimed in the '929 patent is described in, or reasonably expected from, prior art. A patent claim is invalid if the claimed subject matter "would have been obvious" to a person skilled in the art at the time of the invention. 35 U.S.C. § 103(a). A claimed invention is obvious if it merely arranges old elements, each performing its known function, to achieve a reasonably expected result. *KSR Int'l v. Telefex, Inc.*, 550 U.S. 398, 416-17, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results"). A court should utilize common sense when analyzing obviousness. *Id*. at 421.

Celsis's "novel" method uses three well-understood techniques (cryopreserving hepatocytes, thawing cryopreserved hepatocytes, and separating viable from non-viable hepatocytes after thawing using a density gradient). (*See* Gupta Report ¶¶ 33-37.) These three

techniques are arranged into a five-step process: (1) cryopreserving hepatocytes; (2) thawing them; (3) separating viable hepatocytes from non-viable hepatocytes by density gradient fractionation; (4) cryopreserving the viable hepatocytes; and (5) thawing those hepatocytes. Cursory examination of the '929 patent specification reveals that, taken individually, none of these steps is novel. This is precisely what led the PTO to repeatedly reject Celsis's "invention" as obvious. (Exs. 6; 8; 10.) Indeed, Dryden admitted that he did nothing new or different in conjunction with any of these steps. (Ex. 25 (Dryden Dep.) at 22, 24-25, 26-28, 32-33, 59-65.) For example, with respect to the second cryopreservation, the inventor testified:

> Q: Okay. And, specifically, that second cryopreservation was performed using fairly standard cryopreservation techniques, is that accurate?
>
> A: They were standard to me. They're SOPs.
>
> * * *
>
> Q: Did you contribute anything to that field of knowledge or endeavor at that point?
>
> A: Oh, I have no idea.
>
> Q: Again, was the second cryopreservation performed using the same general technique that was used to freeze the cells the first time?
>
> A: Yes.

(*Id*. at 61-62.)

Dr. Li, who has been involved in hepatocyte research for three decades, also describes the routine nature of Celsis's methods. (Li Decl. ¶¶ 3-6.) Based on his research and the findings of the scientific community as of the 2000s, he had "fully expected that cryopreserved human hepatocytes could be thawed, pooled, then refrozen using conventional techniques and have expected viability of 70% or greater when thawed for use." (Li Decl. ¶ 5.) Indeed, when multi-cryopreserved hepatocytes became commercially viable, he developed a multi-cryopreservation process. It took Dr. Li all of one day to combine these steps well known in the field. He

independently developed the same five-step multi-cryopreservation process using the methods "that were by then well established, overwhelmingly accepted, and commonly used and published by the scientific community, including drug researchers." (*Id*. ¶ 6.) The '929 patent "does not describe any new technology. The techniques described in the Dryden patent for the preparation of multi-cryopreserved hepatocytes had all been well established–and documented in the literature–prior to 2005." (*Id.*) Similarly, one of ordinary skill in the art would understand that the '929 patent teaches no new techniques of cryopreserving, thawing, or isolating viable cells after a thaw. (Gupta Report ¶¶ 35, 37.)

In fact, the prior art cited in Terry *et al.*, but deleted by Celsis in its response to the PTO's rejection, shows that combining the five steps leads to a reasonably expected result. *See* Gupta Report ¶¶ 27-45. Ulrich *et al.* and de Sousa *et al.* teach that cryopreservation (without separating viable from non-viable hepatocytes) decreases hepatocyte viability by 5-15%. (Gupta Report ¶ 29.) De Sousa *et al.* further teaches that separating viable from non-viable hepatocytes after cryopreservation can increase post-cryopreservation hepatocyte viability to more than 90%. (Gupta Report ¶27.) Thus, by combining this prior art, one of ordinary skill in the art would have reasonably expected that, after the first cryopreservation and separation of viable from non-viable hepatocytes, more than 90% of the hepatocytes in the sample would be viable. One of ordinary skill in the art would have further reasonably expected that a subsequent cryopreservation and thawing (without further separation) would result in hepatocyte viability of 75-85% (a reduction of 5-15%). This is precisely the result claimed as novel by Celsis (*e.g.*, freeze, thaw, separate, freeze, thaw, leading to more than 70% hepatocyte viability).

In fact, the repeated freezing and thawing of hepatocytes with viabilities above 80% had been achieved and reported by 2002 by Mahli *et al*. (Gupta Report ¶ 28, Ex. 13.) One of

ordinary skill in the art would have known, with a reasonable expectation of success, how to combine the known techniques to produce hepatocytes with viabilities exceeding 70%. (Gupta Report ¶¶ 25-45.)

Because the '929 patent's non-novel steps lead to a reasonably expected result, it is invalid for obviousness under § 103.

3. The '929 Patent is Invalid for Lack of Written Description.

The '929 patent is invalid because the named inventors failed to disclose in the specification the prohibition on plating required by claims 1 and 10.

Patent claims that exceed the scope of the invention's description in the specification are invalid. *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351, 1358 (Fed. Cir. 2010) (noting that 35 U.S.C. § 112 contains a written description requirement distinct from that section's enablement requirement). Consequently, "[w]hat is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue." *Id*. at 1347 (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002); *see Ariad*, 598 F.3d at 1352 ("[I]t is the specification itself that must demonstrate possession.").

Furthermore, if a claim contains a negative limitation not described in the patent's specification or in the original claims, it lacks descriptive support and is invalid. *Ex parte Grasselli*, 231 U.S.P.Q. (BNA) 393, 394 (B.P.A.I. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984); s*ee also Ex parte Tao Xie*, 2008 WL 5232784, *2 (B.P.A.I. 2008) (unpublished) (citing and applying *Grasselli*). "With regard to negatively claimed features and the written description requirement, the critical question is whether such negatively claimed features introduce new concepts." *Tao* at *2. The description requirement, thus, polices against negative limitations designed to avoid prior art.

Indisputably, the specification and originally filed claims do not teach that the invention requires no plating of hepatocytes between the first and second cryopreservations. (*See* Exs. 1; 24.) One of skill in the art would not find support in the specification and the original claims for the prohibition against the plating of hepatocytes between the first and second cryopreservations. (Gupta Report ¶¶ 22-24.) Indeed, Celsis introduced the concept of not plating into claims 1 and 10, after the application was filed, in order to avoid the prior art. More specifically, in response to a rejection by the Examiner that the inventions were obvious in light of the prior art, Celsis amended all claims to include the "wherein the hepatocytes are not plated between the first and second cryopreservations" limitation. (*See* Ex. 6, Ex. 12 at 3-6.)[5] Although Celsis claimed that support for the amendments "is found throughout the specification and the originally filed claims," (Ex. 12 at 6), Celsis did not show where that support could be found – nor could it because no support exists. Because there is simply no descriptive support for the later-added "no plating" limitation, the patent is invalid for lack of an adequate description.

4. LTC Does Not Infringe the '929 Patent.

LTC does not infringe upon the Celsis patent for numerous reasons explained below.

a. Construction of the Phrase "Preparation of Multi-Cryopreserved Hepatocytes" Must Include Density Gradient Centrifugation.

Before assessing alleged infringement, the court construes claims as a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Expert testimony, such as that proffered by Celsis's Dr. Strom, is disfavored in

[5] The August 15, 2008 amendment further included the negative limitation "without requiring a density gradient step after thawing the hepatocytes for the second time. . ." (Ex. 12.) This negative limitation also lacks written support and was rejected by the Examiner as new matter. (Ex. 16 (November. 13, 2008 Office Action) at 16.) Celsis argued in response that the specification and/or originally filed claims did not recite a requirement for a density gradient step after the second thaw, and therefore they were entitled to exclude this step. (*See, e.g.* Ex. 17 (February 12, 2009 Response) at 17.) The Examiner ultimately withdrew the new matter rejection based on Celsis's argument. (See Ex. 23.) The Examiner made a clear error in contravention of the requirements of MPEP 2173.05(i.), which elegantly and succinctly states: "The mere absence of a positive recitation is not basis for an exclusion." Accordingly, claims 1-11 are invalid for reciting this negative limitation absent written support.

construing claims. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1318-19 (Fed. Cir. 2005)). Accordingly, no weight should be given to the proposed claim constructions given by Dr. Strom, which is unsupported in any event.

Celsis's proposed construction of "**preparation of multi-cryopreserved hepatocytes**" is inconsistent with the language of the patent and the file wrapper. Celsis characterized this phrase in its patent as including "a composition of hepatocytes that have been frozen and thawed at least two times . . . ." (Ex. 24 ('929 patent) at col. 5 ln. 45-51.) Yet, in its motion, Celsis proposes to add the phrase "according to the claimed process." (*See* Pl. Motion at 10.) Addition of this phrase is not supported by specification and file history.

However, the patent's file wrapper makes clear that the definition of this phrase must include density gradient fractionation prior to the second freeze. (*Id. at* col. 19 ln. 61-63.) The prosecution history establishes that Celsis understood that a Percoll density gradient step was a required feature of all claims.[6] In order to overcome the PTO's rejection to all pending claims (including pending claim 20, which became issued claim 10) due to lack of written description, Celsis argued that "the claims require only that Percoll™ density gradient centrifugation is performed *prior* to refreezing." (Ex. 17 (Feb. 17, 2009 Amendment) at 17 (emphasis in original).) This requirement was significant enough that Celsis reaffirmed the need for it in its next amendment. (Ex. 19 (June 22, 2009 Amendment) at 17.) Further, Celsis repeatedly acknowledged that any "preparation of multi-cryopreserved hepatocytes" must have been prepared using density gradient fractionation before the second freezing step. Based on Celsis's amendment and acknowledgements, the Examiner allowed the claims to issue.

[6] In his deposition, the inventor confirmed this step as a required feature of the patent. (Ex. 25 (*See* Dryden Dep. at 32-33, 58-59)).

Thus, the term "preparation of multi-cryopreserved hepatocytes" should be construed as meaning "a hepatocyte preparation that has been frozen and then thawed at least two times with a Percoll^{TM} density gradient centrifugation performed prior to the second freeze."

b. Neither LTC Nor Its Customers Performs All Steps of Either Claim 1 or Claim 10 of the '929 Patent.

Neither LTC nor its customers have infringed either claim 1 or claim 10 of the '929 patent because neither performs each step of the claimed methods. LTC does not perform the second thaw (as required by claims 1 and claim 10), or the incubation or determination (as required by claim 10). (Supplemental Declaration of Marcus J. Hunkeler ("Hunkeler Supp. Decl.") ¶ 8.) LTC customers do not perform a Percoll density gradient centrifugation following a first preservation and thaw, or a second cryopreservation (as required by both claim 1 and claim 10). (*Id.*) LTC does not control or direct the customers' use of the frozen cells. (*Id.*)

This situation does not give rise to patent infringement. In *BMC Resources v. Paymentech, L.P.*, the Federal Circuit clarified the standard for when a method claim may be infringed by the combined actions of multiple parties. 498 F.3d 1373, 1378-79 (Fed. Cir. 2007). The Court held that direct infringement generally occurs only where a *single party* performs *every step* of a claimed method. 498 F.3d at 1380. Where the actions of multiple parties combine to perform every step of a claimed method, the claim is directly infringed *only* if one party exercises "control or direction" over the entire process such that *every step* is attributable to the controlling party. *BMC Resources*, 498 F.3d at 1380-81. This control or direction is present where one party is the "mastermind." *Id.* at 1381. A mere "arms-length cooperation" does not give rise to direct infringement by a party. *Id.* at 1381.

LTC does not control or direct its customers, nor do the customers have control or direction over LTC. (Hunkeler Supp. Decl. ¶ 8.) Simply put, because LTC does not perform

every step of a claimed '929 patent method, it is not liable for patent infringement. Furthermore, because there is no direct infringement, there can be no inducement or contributory infringement under §§ 271(b) and (c). *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993).

c. LTC Does Not Infringe the '929 Patent Under § 271(a), (b), or (c) With Respect to Any Methods in Which One or More Steps are Practiced Outside the United States.

A method claim is not infringed under § 271(a), (b), or (c) if one or more steps are practiced outside the United States. *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005) (with regard to infringement under § 271(a)); *Joy Technologies*, 6 F.3d at 774. (no infringement under §§ 271(b) or (c) absent existence of infringement under § 271(a)). LTC does not infringe under § 271(a), (b), or (c) if it creates or uses multi-cryopreserved hepatocytes outside the United States.

d. LTC Products Cryopreserved Before October 20, 2009 Do Not Infringe the '929 Patent.

A method claim is not infringed if one or more steps are practiced before the issuance of the patent. *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1360 (Fed. Cir. 2007). In this case, the '929 patent did not issue until October 20, 2009. Accordingly, no infringement of the '929 patent can occur by a product manufactured by LTC if even the first cryopreservation step of the final product was performed prior to October 20, 2009.

e. Methods That Do Not Employ a Density Gradient Fractionation Step Do Not Infringe the '929 Patent.

A wide variety of methods exist for the isolation and separation of cells based on their physical properties, including lysis, plastic adherence, elutriation and density gradient centrifugation. (Ex. 27 at 46, 48.) Claim 1 of the '929 patent describes the use of "density gradient fractionation" to separate the viable and non-viable hepatocytes prior to the second cryopreservation step. Further, claim 10 of the '929 patent, while not explicitly reciting a density

gradient fractionation step, implicitly requires such a step because Celsis argued during prosecution of the '929 patent that a density gradient centrifugation was required by all of the claims[7]. Thus, all methods for the isolation and separation of cells that do not rely upon density gradient fractionation, such as the non-gradient density fractionation technique used by LTC in making the accused products, do not infringe the '929 patent.

During the prosecution of the '929 patent, Celsis asserted that Percoll density gradient centrifugation was part of the multi-cryopreservation process. In the November 13, 2008 Office Action, the Examiner asserted rejections under 35 U.S.C. § 112, first paragraph, for new matter and also for lack of enablement. (Ex. 16.) In the February 12, 2009 response to that rejection, Celsis stated "[w]hile Applicants understand the premise that Percoll™ density gradient centrifugation will remove non-viable cells, the claims require only that Percoll™ density gradient centrifugation is performed *prior* to re-freezing." (Ex. 17 at 17 (emphasis in original).) Celsis repeated this same argument in its June 22, 2009 response to the PTO. (Ex. 19 at 17 (emphasis in original).)

Based on these assertions, Celsis cannot now assert that "density gradient fractionation" is not a required part of the '929 patent's method claims. Amendments and arguments made to overcome rejections under §112 may give rise to an estoppel. *See Honeywell Int'l Inc., v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1142 (Fed. Cir. 2004)(en banc). Arguments made during prosecution can be given the same weight as claim amendments. *Elkay Manufacturing Co. v. Ebco Manufacturing Co.*, 192 F.3d 933, 979 (Fed. Cir. 2000). "Clear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim, may create an estoppel." *Southwall Technologies, Inc. v. Cardinal IG*

[7] That would include then pending claims 10-17 and 19-22, which ultimately issued as claims 1-11. (Ex. 23 at 2)

Co., 54 F.3d 1570, 1583 (Fed. Cir. 1995) (citing *Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 988 F.2d 1165, 1174 (Fed. Cir. 1993)).

Celsis's arguments, made in response to outstanding rejections of the claims that would ultimately issue in the '929 patent, require that a "density gradient fractionation" be performed prior to re-freezing the hepatocytes in order for the claims to be infringed. In that respect, Celsis is now estopped from any claim interpretation that would read out the required step of performing a density gradient fractionation step in claims 1-11 of the '929 patent.

LTC does not infringe the '929 patent because LTC does not use a density gradient fractionation step to create multi-cryopreserved hepatocytes. Rather, LTC utilizes an iso-density centrifugation step to separate viable and non-viable hepatocytes. (Hunkeler Supp. Decl. ¶ 7.) An "iso-density" centrifugation refers to the fact that the cells are separated in a solution that has uniform (as opposed to gradient) density. (*Id*.) Since its first production run, LTC (then CellzDirect) has used the methodology developed by Dr. Ed LeCluyse (the founder of CellzDirect.) (*Id*. ¶ 6) This methodology is described in Dr. LeCluyse's 2005 publication in the journal Methods in Molecular Biology (Hunkeler Supp. Decl., Ex. A.) In essence, the LTC protocol includes the separation of viable hepatocytes during a low speed spin in an iso-density Percoll solution.

Although the '929 patent claim step "density gradient centrifugation" plainly requires the use of a gradient, in an attempt to obfuscate this necessary element, Celsis proposes the definition "a process for separating viable hepatocytes based on their density." (Pl. Motion at 10.) While this definition may be partly true (in that the cells are separated based on their density and their density alone), the plain meaning of the term "density gradient fractionation" necessarily requires that the density separation be done in and based on a gradient. LTC's

process does not infringe if the claim is properly construed because it does not use a density gradient fractionation step.

B. CELSIS WILL NOT SUFFER IRREPARABLE HARM.

In order to obtain a preliminary injunction, Celsis must prove it would be irreparably harmed absent such relief. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391, 126 S.Ct 1837, 164 L.Ed.2d 641 (2006). In *eBay*, the Supreme Court rejected the presumption of irreparable harm in patent cases, cautioning against a "categorical grant" of injunctive relief upon a finding of validity and infringement. *Id*. at 393-394; *see also Tiber Laboratories v. Hawthorn Pharmaceuticals, Inc.*, 527 F. Supp. 2d 1373, 1380 (N.D. Ga. 2007) ("*eBay* does not leave room for a presumption of irreparable injury in patent cases, whether raised at the preliminary or permanent injunction phase.").

To show irreparable harm, a plaintiff must prove that it cannot be compensated with monetary damages. *Id.* at 1381. "[N]either the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial." *Nutrition 21*, 930 F.2d at 871 (internal citation omitted).

Celsis claims that LTC's actions have forced it to lose sales, lower prices, suffer harm to its goodwill, and spend time managing litigation. (Pl. Motion at 11-13.) Every one of these harms is monetary in nature and can be addressed by Celsis's request for damages. For example, one can readily calculate damages from alleged lost sales. Indeed, Celsis itself purports to quantify with precision its alleged damages from lost sales. (Decl. of Judy Madden ¶ 15-17.) Price erosion is also readily compensable by money damages. *Novartis Pharm. Corp. v. Teva Pharms. USA, Inc.*, 2007 WL 2669338, at *14 (D. N.J. 2007) (unpublished). Celsis proffers

evidence in an attempt to quantify monetary damages from decreased sale prices. (*See* Madden Decl. ¶¶ 20-22.)

Celsis's failure to seek preliminary injunctive relief against other allegedly infringing products also undercuts its claim that a preliminary injunction is necessary to prevent irreparable harm. *See Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, 2005 WL 2063785, at *5 (M.D. Fla. 2005) (unpublished) (holding no irreparable harm, "particularly since this market already includes [allegedly infringing products against which plaintiff] has not sought preliminary injunctive relief"). Celsis previously filed a patent infringement case against Xenotech, LLC and its parent company asserting nearly identical claims of patent infringement that it now asserts against LTC. *Celsis in Vitro, Inc. v. Xenotech, LLC*, (Case No. 10 cv 0681) (N. D. Ill.) Significantly, in the *Xenotech* litigation, Celsis never requested preliminary injunctive relief. (*See* Ex. 26 (*Celsis v. Zenotech, et al.* Complaint) (requesting damages and a *permanent* injunction).)

Celsis's claim that it will suffer irreparable harm is further undermined by its delay in prosecuting this action. LTC has manufactured, marketed and sold pooled multi-cryopreserved hepatocytes since the first quarter of 2008. By Celsis's own admission, it has been aware of LTC's alleged patent infringement during this entire period. (Complaint ¶ 20.) Nevertheless, Celsis did not request an accelerated patent review, and did not commence this action until eight months after the patent issued.

In an effort to support its claim that it will suffer irreparable damages due to LTC's actions, Celsis states that it "**has never licensed [the '929 patent] to another competitor** . . . ." (Pl. Motion at 13 (emphasis in original).) Even if true, Celsis's failure to obtain licensing fees is not for lack of trying. Indeed, in Celsis's *Xenotech* litigation, Celsis admitted that it provided

written notice to Xenotech " identifying the [Xenotech] products *as potentially requiring a license under the '929 patent . . . .*" (Ex. 26 (*Celsis v. Xenotech* Complaint) ¶ 20.). This request demonstrates that any damages for alleged infringement of Celsis's patent are both monetary and quantifiable.

C. THE BALANCE OF HARDSHIPS FAVORS LTC.

A court is not required to make findings regarding the balance of hardships or the public interest where a plaintiff has not demonstrated both a likelihood of success and irreparable harm. *See Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1356 (Fed. Cir. 2002). Because Celsis has failed to demonstrate these two requirements, this Court need not analyze a balance of hardships or the public interest. If the Court reaches these factors, they provide further evidence why a preliminary injunction should not issue.

"An injunction should not be granted if its impact on the enjoined party would be more severe than the injury the moving party would suffer if it is not granted." *Litton Sys., Inc. v. Sundstrand Corp.*, 750 F.2d 952, 959-61 (Fed. Cir. 1984). If the preliminary injunction is granted in this case, LTC will be excluded from the multi-preserved hepatocyte market. CellzDirect is small division, with approximately 60 people based out of Durham, NC. (Hunkeler Suppl. Decl. ¶ 4.) As described by LTC's Director of Product Development and Marketing, the temporary restraining order in this case has already effectively shut down not only CellzDirect's distribution of hepatocytes, but all of its hepatocyte product development. (*Id.*) Although LTC fully expects to prevail at trial in this matter, that victory will be a Pyrrhic one if a preliminary injunction is granted: CellzDirect will lose substantial portions of its business if it cannot sell pooled multi-cryopreserved hepatocyte products to its customers or even develop new products. (*Id.*) A preliminary injunction would cost LTC approximately $1 million a year. (Hunkeler Decl. ¶ 8-10).

Conversely, if the Court denies the injunction, Celsis will be free to continue marketing and selling its products. If Celsis further prosecutes this action and prevails, it can be compensated for any of its proven interim damages.

D. THE PUBLIC INTEREST FACTOR FAVORS LTC.

In its analysis of the public interest, Celsis cites a generic policy of favoring patent rights. However, there is a "significant public policy interest in removing invalid patents from the public arena." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1354 (Fed. Cir. 2005). One of the Court's roles in evaluating whether to grant a preliminary injunction is to protect the interests of the public, who are obviously unrepresented at these proceedings. The public has an interest in preventing competition from being "repressed by worthless patents." *Id.*

Where a party fails to make a clear showing of likelihood of success on its claim, "the public interest in the enforcement of valid patents does not trump the public interest in competition." *Cummins-Allison Corp. v. Glory Ltd.*, 2003 WL 355470, *52 (N.D. Ill. 2003) (unpublished); *see also Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990) (addressing a party's continuing right to compete in the marketplace). By Celsis's own admission, it seeks to restrict access and increase prices for a method that promotes the discovery of potentially life saving drugs. (*See generally* Decl. of Judy Madden.)

The public would be harmed if the Court removed the CellzDirect product from the market. As set forth in the Hunkeler Supplemental Declaration, the end users of the CellzDirect cryopreserved pooled hepatocytes are scientists responsible for researching drug metabolism and safety. (Hunkeler Suppl. Decl. ¶ 5.) A basic tenet of drug research is that scientists should maintain consistency throughout the duration of their research. Since the temporary restraining order, CellzDirect's long-term customers in research institutions and in the industry have been

unable to rely on CellzDirect to supply hepatocytes. (*Id.*) Extending this onerous restriction will continue to disrupt scientific research. (*Id.)*

Even if the scientific community scrambles to obtain hepatocytes from other sources, a preliminary injunction will represent a significant setback for researchers. CellzDirect is known for providing pooled multi-cryopreserved products that exhibit higher metabolic activity and better consistency than other suppliers. (*Id.* ¶ 3*).* Removing the CellzDirect products from the research market will necessarily lead to less diversity in hepatic cell lines available to researchers, thus adversely affecting the quality and reliability of all research in the field. (*Id.* ¶ 5.)

Accordingly, the public interest strongly weighs against granting Celsis's requested extraordinary relief. This factor is especially persuasive in light of Celsis's highly questionable chance of prevailing in this matter.

IV. CONCLUSION

Celsis is not entitled to the drastic and extraordinary remedy of a preliminary injunction, rarely granted in patent cases, because it cannot show a likelihood of success on the merits. At a minimum, LTC has raised substantial questions concerning enforceability, validity, and infringement of the '929 patent, making the issuance of interim relief inappropriate.

The '929 patent is not enforceable because of Celsis's inequitable conduct: Celsis intentionally and repeatedly submitted misleading and deceptive information to the PTO to overcome the Examiner's rejection of the application for obviousness. Furthermore, the '929 patent is in fact invalid because of obviousness: the claimed methods simply combined methods well-known in the prior art, and they are not entitled to patent protection. In addition, the '929 patent is invalid because it violates the statutory written description requirement: the patent's

claims are not described in the specification. Moreover, LTC has not infringed the patent for multiple reasons. Finally, Celsis cannot meet the other requirements for injunctive relief because it has not suffered irreparable harm and it has an adequate remedy at law, and both the balance of hardships and public interest factors favor defendants.

Plaintiff's motion for preliminary injunction should be denied.

DATED this 30th day of July, 2010.

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CERTIFICATE OF SERVICE

I hereby certify that on the 5th day of August, 2010, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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